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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,552	08/23/2006	Yoshitaka Ito	10873.1940USWO	6707
53148 7590 02/16/2010 HAMRE, SCHUMANN, MUELLER & LARSON P.C. P.O. BOX 2902-0902 MINNEAPOLIS, MN 55402				
EXAMINER				
BHAT, NARAYAN KAMESHWAR				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
02/16/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,552

Applicant(s)

ITO ET AL.

Examiner

NARAYAN K. BHAT

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56, 59-63, 66, 69 and 72 is/are pending in the application.
- 4a) Of the above claim(s) 61-63, 66, 69 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

1. This action is in response to the papers filed on October 7, 2009. Applicant's claim amendments requiring additional limitations necessitated new grounds of rejections presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

Claim Status

2. Claims 56, 59-63, 66, 69 and 72 are pending in this application. Claim 56 is amended. Claim 73 is cancelled. Claim amendments have been reviewed and entered. Applicant's arguments filed on October 7, 2009 have been fully considered and addressed following rejections. The previous rejections under 35 USC § 102 or 103 not reiterated below have been withdrawn in view of claim amendments.

3. Claims 61-63, 66, 69 and 72-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention of group II to IV there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 28, 2009 and made final on July 7, 2009.

4. Claims 56, 59 and 60 are under prosecution.

Election/Restrictions

5. Applicants further argue that claim 56 provide the special technical feature common to all the claims and that restriction requirement is improper (Remarks, pg. 6, paragraph 2). This argument is not persuasive because as described in the office action

mailed April 1, 2009 and July 7, 2009, the common technical feature is a microarray device comprising a substrate on which at least one probes is immobilized to detect bacteria associated with degradation of organochlorine compound. However, a microarray device for detecting bacteria associated with degradation of organochlorine compound is taught by Deneff et al. Furthermore, as described in the office action mailed on July 7, 2009, Scott et al teaches a device comprising 40-mer probes to detect and distinguish 18 different types of bacteria associated with PCE degradation pathway at the same time. Also, Applicants have acknowledged that Scott et al teaches 40-mer probes to detect and distinguish 18 different types of bacteria associated with PCE degradation pathway (Remarks, pg. 6, paragraph 2). Therefore, the technical feature linking groups I to IV does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirements for unity of invention. Therefore the lack of unity requirement is still deemed proper and **therefore made FINAL.**

Note to Applicants

6. Examiner thanks Applicants for providing requested material used by Scott et al for a poster presented at the Society for Biotechnology, Japan in 2003.
7. The instant claim listing includes the withdrawn claims 61-63, 66, 69 and 72, drawn to a nonelected invention of group II-IV and made final in the office action mailed July 7, 2009. Per 37 CFR 1.121, the current status of all of the claims in the application,

including any withdrawn claims, must be given and their status is indicated in a parenthetical expression following the claim number by the status identifiers: (withdrawn). The status identifier (withdrawn- currently amended) is also acceptable for a withdrawn claim that is being currently amended (MPEP, 37 CFR 1.121, and section c). Applicants are requested to identify the claims 61-63, 66, 69 and 72 with proper identifier, i.e., (Withdrawn) following the claim number.

Claim Objections

8. Previous objections to claim 56 are withdrawn in view of claim amendments for correcting multiple periods.

Claim Rejections - 35 USC § 102/103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 56, 59 and 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scott et al (Document provided by Applicants, October 10, 2009 –Material presented at The society for Biotechnology, Japan, 55th meeting 2003).

Regarding claim 56, Scott et al teaches a method of judging a biological activity in an environment contaminated with an organochlorine compound tetrachloroethylene (PCE) as claimed.

Scott et al teaches a method comprising amplifying a nucleic acid extracted from an environmental sample by a gene amplification method so as to use the amplified product as a target (pg. 11/33, pg. 21/33 and pg. 22/33) and further teaches hybridizing the target to a DNA probe including a base sequence unique to each of 17 types of anaerobic bacteria denoted as A to Q, which are related to degradation of the organochlorine compound, in an attempt to detect the 17 types of bacteria in the environment (pg. 11/33, pg. 19/33, pg. 23/33 and pg.24/33).

Scott et al also teaches judging capability of the environment to eliminate the organochlorine compound based on degrading capability of the each of 17 types of

bacteria that is detected with respect to the organochlorine compound and a dechlorinated product thereof (pg. 19/33).

Scott et al also teaches that the DNA probe is a combination of at least 126 types of DNA probes each of which is unique and bonded specifically to an internal transcribed region of any one of the 17 types of bacteria denoted as A to Q without occurrence of cross-hybridization (pgs. 26/33 to 32/33).

It is noted that Scott et al teaches that the ITS sequence for probe construction for the microarray (pg. 22/33 and pg. 24/33) and chooses 2-7 unique probes (pg. 23/33) for each bacteria, which encompasses probes without occurrence of cross hybridization. Instant claim 56 as recited requires DNA probe is a combination of 87 types of DNA probes represented by SEQ ID NOS 19-87 (form 1) or simply a base sequence complementary to the each of the 87 types of probes (form 4). It is noted that form (4) as recited does not require sequence to be identified by SEQ ID NOS. Scott et al also uses 40 mer sequences to find hits in the nucleotide data base in GenBank (pg. 23/33), thereby suggesting the sequence information of all 40-mer probes at the time of the poster presentation in 2003. Therefore, absent factual evidence by Applicants, the primers and probes disclosed by Scott et al at 2003 meeting is reasonably interpreted as the base sequence or complementary to each of the base sequence of SEQ ID NOS 19-105.

Regarding claim 59, Scott et al teaches a gene amplification method using a sense (i.e., forward) and an antisense primer (i.e., reverse) primers containing a polynucleotide sequence (pg. 22/33).

Regarding claim 60, Scott et al teaches that the contaminated environment is selected from soil and water (pg. 11/33).

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Scott et al are silent with regard to SEQ ID NOS 19-105 and 116 and 117. However, as described above, Scott et al teaches that the primers for DNA amplification from the environment sample and DNA probes on the array are specific to any one of the 18 types of PCE degrading bacteria and are able to detect any potential PCE degrading bacteria in the soil, thus anticipates the claimed invention.

Alternatively, it would have been obvious to one of ordinary skill in the art to use the 16S-23S –ITS region sequence from 'A' to 'Q' bacteria and design the probe comprising SEQ ID NOS 19-105, which are also for judging a biological activity in an environment contaminated with PCE as taught by Scott et al (pg. 11/33).

The burden is on the Applicant to show that the claimed single combination of probes comprising SEQ ID NOS 19 to 105 and 'A' to 'Q' bacteria are non-obvious over the teachings of Scott et al.

13. Claims 56, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al (Document provided by Applicants, October 10, 2009 –Material presented at The society for Biotechnology, Japan, 55th meeting 2003) in view of Buck et al (BioTechnique, 1999, 27, 528-536).

Following rejection is made for Scott et al not explicitly (pending factual evidence by Applicants) teaching nucleic acid sequence of SEQ ID NOS 19-105, 116 and 117.

Teachings of Scott et al regarding claims 56, 59 and 60 are described above in section 12. Scott et al also teaches using ITS sequence information to design 40-mer probes (pg. 22/33) and further teaches also using 40 mer sequences to find hits in the nucleotide data base in GenBank (pg. 23/33). Scott et al explicitly do not teach sequence of probes and primers with SEQ ID NOS 19 to 105, and 116 and 117. However, primers and probes for nucleic acid sequences were known in the art at the time of the claimed invention were made as taught by Buck et al.

Buck et al teaches primers/probes for nucleic acid amplification and further teaches that primers/probes for a nucleic acid sequence are generated using software or manually using different criteria (pg. 532, Software or Manual section of primers section). Buck et al also teaches 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby generating more than 1/3 of all possible primers on the 300 base pair sequence (see page 530, column 1). Buck et al further teaches that EVERY SINGLE PRIMER amplifies the target sequence (pg. 533, column 1) even though they are selected using different criteria (pg. 535, Discussion section) thus teaching every primer would have a reasonable expectation of success to detect PCE degrading bacteria.

As described above, Scott et al teaches a prototype sequence identities of Desulfobacterium species (pg. 20/33) and further teaches using ITS sequence for designing and producing 40 mer probe construction (pg. 22/33). Scott et al also teaches using 40 mer sequences to find hits in the nucleotide data base in GenBank (pg. 23/33) thereby demonstrating the Scott et al had possession of the sequence information

before the time the application was filed. Burke et al teaches nucleic acid sequence of primer probes for nucleic acid amplification. Combined teaching of Scott et al and Buck et al would provide nucleic acid sequence comprising SEQ ID NOS 19-105 and 116-117 as claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to design probes and primers that are equivalent to those claimed as SEQ ID NOS 19-105 and 116 and 117. The ordinary artisan would be motivated to design probes and primers that work in an equivalent fashion to those of SEQ ID NOS 19-105 and 116 and 117 because Buck et al teaches any primer will amplify the nucleic acid sequence of interest. The ordinary artisan would be motivated to use an alternative primer set with a reasonable expectation of success, because Buck teaches all primers work. The claimed SEQ ID NOS 19-105 and 116 and 117 are therefore obvious over Scott et al and Buck et al, absent secondary considerations and factual evidence showing 40 mer probe Scott et al are different from the claimed SEQ ID NO 19 to 105 or their complementary sequence and unexpected results from SEQ ID NOS 19-105, 116 and 117 over the 126 unique probes of Scott et al (7 probes / bacterial species listed in page 27/33).

Response to remarks from Applicants

Claim Rejections - 35 USC § 102/103

14. Applicant's arguments filed October 7, 2009 with respect to claims 56, 59 and 60 as being anticipated by or in the alternative, being obvious over Scott et al have been

fully considered (Remarks, pgs. 7 and 8). These arguments are not persuasive for the following reasons.

Applicants argue that Scott et al do not disclose the sequence of the probes, or the sequence of the primers that were used to obtain the probes. Moreover, nothing in Scott et al teaches or suggests that the probes that were obtained could be combined and used as a single DNA probe and detect any one of the 17 types of bacteria denoted as A to Q without any occurrence of cross-hybridization as recited in claim 56 (Remarks, pg. 7, paragraph 5). These arguments are not persuasive because Applicants have acknowledged that Scott et al disclose several unique probes detecting and distinguishing 18 bacterial species associated with PCE biological activity (Remarks, pg. 7, paragraph 5, and lines 1-3). As described above in sections 12 and 13, Scott et al teaches probes are unique for the bacteria A to Q as claimed and further teaches probes distinguishes different subspecies (pg. 28/33) which encompasses probes are specific without any occurrence of cross hybridization.

Applicants further submit that art remains unpredictable as to the design of probes that are highly sensitive and highly specific, where more than few types of probes are used especially where more than one type of closely related species are tested for hybridization (Remarks, pg. 8, paragraph 1). Applicant's assertion is noted. However, Scott et al teaches probe specificity for more than one type of closely related species are tested for hybridization (pg. 12/33, pg. 13/33, pg. 25/33 and pg. 28/33).

Even if the Applicant's alleged assertion is correct, Applicants have not provided any support documents or factual evidence showing that the probes of Scott et al are

not specific or cross hybridizes with non target sequence. Furthermore, the arguments of counsel cannot take the place of evidence in the record (In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. As described above in sections 12 and 13, Scott et al teaches probes that highly sensitive and highly specific and therefore arguments are not persuasive.

Applicants further argue that Scott et al fail to provide any experimental data or fail to provide or any guidance as to achieving a DNA probe that is combination of as many as 87 types of DNA probes, where each of the 87 types of DNA probes are capable of binding to the ITS region of any of the 17 types of bacteria without any occurrence of cross hybridization as recited in claim 56 with a reasonable expectation of success (Remarks, pg. 8, paragraph 1). These arguments are similar to the one made before and are not persuasive for the same reasons as described above.

As described above in sections 12 and 13, instant claims 56, 59 and 60 are being anticipated by Scott et al or being obvious over Scott et al and Buck et al absent secondary considerations and factual evidence showing 40 mer probe Scott et al are different from the claimed SEQ ID NO 19 to 105 or their complementary sequence and unexpected results from SEQ ID NOS 19-105, 116 and 117 over the 126 unique probes of Scott et al (7 probes / bacterial species listed in page 27/33).

Claim Rejections - 35 USC § 103

15. Applicant's arguments filed October 7, 2009 with respect to claims 56, 59 and 60 as being obvious over Ebersole et al in view of Buck have been fully considered (Remarks, pgs. 8 and 9). These arguments are moot in view of amended claims, withdrawn rejections and new grounds of rejections set forth in this office action necessitated by claim amendments.

Conclusion

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634